K021171

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16.4 DEVICE DESCRIPTION

The Q-Stress Echo™ Bed is a complete integrated stress echocardiography system. The Q-Stress Echo™ Bed combines the Stress Echo™ Bed / Table with an electrocardiograph. The Stress Echo™ Bed provides an exercise source that delivers programmable, controlled variable resistance, while the ECG provides the patient monitoring and recording. Several models of the Stress Echo Bed/Table are available with features that include height adjustability, Trendelenburg, dual, lateral tilt, and computer controllers.

16.5 SUBSTANTIAL EQUIVALENCE

The Q-Stress Echo™ Bed is substantially equivalent to the Vertex System in commercial distribution by Medical Positioning. The Q-Stress Echo™ Bed and the predicate device incorporate the same Stress Echo™ Bed and an electrocardiograph. The Q-Stress Echo™ Bed incorporates the Q-Stress electrocardiograph manufactured by Quinton Instruments.

The fundamental technical characteristics of the Q-Stress Echo™ Bed and the Vertex System are equivalent and are listed on the comparison charts provided in this 510(k) submission. The Q-Stress Echo™ Bed and the Vertex System function by providing the user with an integrated exercise source and electrocardiograph for use during cardiovascular monitoring.

16.6 INTENDED USE

The Q-Stress Echo™ Bed is intended for use in stress echocardiography examination. The Q-Stress Echo™ Bed provides an exercise source that delivers programmable, controlled variable resistance.

The Q-Stress Echo™ Bed incorporates an electrocardiograph that records either normal conditions or patterns of arrhythmia and/or rate abnormalities in patients.

In addition, the Q-Stress Echo™ Bed provides "QRS" complex to a cardiac ultrasound device to be used to capture images (heart beats), either digitally or on videotape, such that each image begins at the time systole begins.

16.7 TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Q-Stress Echo™ Bed are equivalent to those of the Vertex System. The Q-Stress Echo™ Bed utilizes a supine bicycle for the exercise source. Preprogrammed exercise protocols are run for purposes of electrocardiographic monitoring. The ECG used in the Q-Stress Echo™ Bed is the Quinton Q-Stress electrocardiograph that has been cleared for commercial distribution under K001492. ECG reports, trends, averages and ST segments are printed by the Q-Stress Echo™ Bed. The Q-Stress Echo™ Bed is connected using standard patient electrodes and leads that are not included in the system.

16.8 PERFORMANCE DATA

The Q-Stress Echo™ Bed was subjected to performance bench testing. Physical performance studies and software evaluation were conducted to verify that the Q-Stress Echo™ Bed performed as intended.

16.9 CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. The Q-Stress Echo™ Bed was found to perform as intended during verification and validation testing. The Q-Stress Echo™ Bed is substantially equivalent to the current Vertex System in commercial distribution. The Q-Stress Echo™ Bed is intended for use in stress echocardiography examination. The Q-Stress Echo™ Bed provides an exercise source that delivers programmable, controlled variable resistance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 8 2002

Medical Positioning, Inc.
c/o Ms. Carol Patterson
President
Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, CA 92630

Re: K021171
Trade Name: Q-Stress Echo™ Bed
Regulation Name: Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulatory Class: Class II (two)
Product Code: 74 DPS
Dated: April 11, 2002
Received: April 12, 2002

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

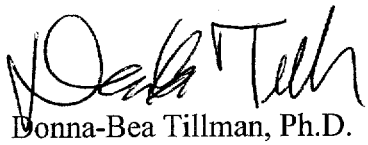
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K021171

Device Name: Q-Stress Echo™ Bed

Indications for Use: The Q-Stress Echo™ Bed is intended for use in stress echocardiography examination. The Q-Stress Echo™ Bed provides an exercise source that delivers programmable, controlled variable resistance.

The Q-Stress Echo™ Bed incorporates an electrocardiograph that records either normal conditions or patterns of arrhythmia and/or rate abnormalities in patients. In addition, the stress echo workstation provides "QRS" complex to a cardiac ultrasound device to be used to capture images (heart beats), either digitally or on videotape, such that each image begins at the time systole begins.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021171

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)